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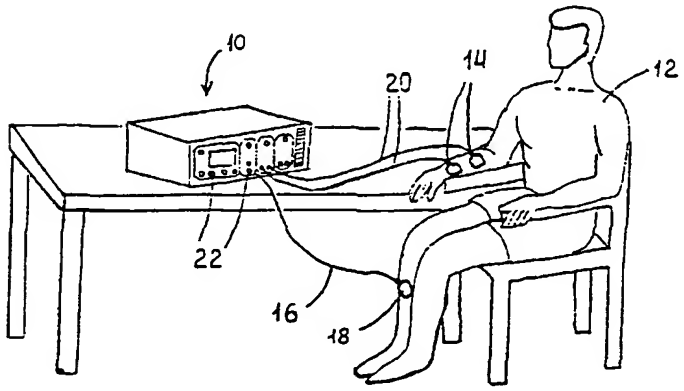
(54) Title: ELECTROSTIMULATION SYSTEM WITH ELECTROMYOGRAPHIC AND VISUAL BIOFEEDBACK




(57) Abstract: The device of the present invention provided an electrostimulation system with electromyographic and visual biofeedback for sensing electromyographic impulses and facilitating muscular activity. The electrostimulation system comprises stimulator that is adapted to generate an electric impulse and at least one pair of electrodes adapted to transmit the electric impulse or to receive electromyographic impulses. The system further comprises an amplifier electrically communicating with the pair of electrodes, the amplifier is adapted to amplify the received electromyographic impulses and a filtering unit electrically communicating with the amplifier and is adapted to remove artifacts from the received electromyographic impulse. A commutation block is electrically communicating with the pair of electrodes and is adapted to alternately transfer the electromyographic impulses to the amplifier or to transfer the generated electric impulse from the stimulator. A display for displaying the received electromyographic impulses and a predetermined threshold value is also provided as well as a control unit that is adapted to receive the electromyographic impulses from the amplifier and to activate the stimulator in a predetermined manner. The stimulator incorporated in the present invention is triggered to transmit impulses to the rehabilitated muscle when the electromyographic impulse substantially equals or exceeds the predetermined threshold value.

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One of the rehabilitation processes used for patients suffering from partial muscle paralysis such as CVA patients is the reeducation of the muscle to conduct voluntary actions. Another example that takes the above considerations into account is US patent no. 4,811,742 "Proportional Response Electrical Muscle Stimulation" filed in 1985 by Hassel et al. This patent discloses measuring the excitation of the skeletal musculature of a subject by an EMG, processing it and controllably applying to the musculature EMG impulses that are proportional to the electrical nerve impulses. This invention is useful for reeducation and/or amplification of muscular control.

The display of the EMG impulses for the selection of transmitted impulses is also a known prior art. Such a device was filed in 1992 and is disclosed in US patent no. 5,300,096 "Electromyographic Treatment Device" by Hall et al. This invention discloses an electrical muscle stimulator that converts EMG impulses to digital words for the analysis and display by a computer program. The therapists selects a variety of different parameters appropriate for the individual patient, and instruct the device to initiate stimulating impulses on command, or upon detection of a suitable EMG impulse from the patient. The device can digitally model a wide variety of waveforms and graphically assist the therapist in developing and shaping various wave pulse trains.

Control over the process of muscles rehabilitation may be achieved upon the combination of transmitting impulses to the muscle similarly to the methods indicated herein above with receiving some indication from the muscle on its function or response. Such combination is disclosed in US patent no. 5,549,656 "Combination Neuromuscular Stimulator and Electromyograph System" filed in 1995 by Reiss. This patent discloses a combined dual channel electromuscular stimulator for directing electrical pulses into the skin and a dual electromyography for detecting electrical impulses generated in muscles. Another example for a controlled system was filed in 1987 and is disclosed by Barry et al. in US patent no. 4,805,636 "System for Controlling Muscle Response". This system for controlling muscular responses in living beings utilizes electrical stimulation of the muscle

It is another object of the present invention to provide an electrostimulation system provided with a display that visualizes the level of EMG impulses produced by the patient.

It is yet another object of the present invention to provide an electrostimulation system in which the therapist feeds the system with predetermined target values to which the patient may reach using his voluntary will. After the patient reaches the target values, the electrostimulation system transmits corresponding stimulation pulses to the patient, in an educational manner.

Additionally, it is an object of the present invention to provide an electrostimulation system provided with the possibility to set the amplitude of a stimulation impulse in conventional stimulation therapy equipment that uses absolute units (milliamperes). The improved system will use threshold units from the EMG measurement for setting the amplitude of the stimulation impulse. Accordingly, the new system permits gradual muscle contraction in a wide range of amplitudes.

It is thus provided an electrostimulation system with electromyographic and visual biofeedback for sensing electromyographic impulses and facilitating muscular activity, said electrostimulation system comprising:

stimulator adapted to generate an electric impulse;

at least one pair of electrodes adapted to transmit said electric impulse or to receive electromyographic impulses;

amplifier electrically communicating with said at least one pair of electrodes, said amplifier adapted to amplify said received electromyographic impulses;

filtering unit electrically communicating with said amplifier, said filtering unit is adapted to remove artifacts from the received electromyographic impulse;

commutation block electrically communicating with said at least one pair of electrodes, said commutation block adapted to alternately transfer the electromyographic impulses to said

when the electromyographic impulse reaches said predetermined threshold value.

Furthermore, in accordance with another preferred embodiment of the present invention, a remote control unit is communicating with said control unit.

Furthermore, in accordance with another preferred embodiment of the present invention, said display is a linear graphic bar display.

Furthermore, in accordance with another preferred embodiment of the present invention, said stimulator comprises:

pulse modulator adapted to construct said electric impulse;

amplitude modulator adapted to set the amplitude of said electric impulse;

CPU unit electrically communicating with said pulse modulator;

Control unit electrically communicating with said CPU unit, said control unit adapted to determine parameters of the pulse modulator and the amplitude modulator;

setting unit adapted to determine a threshold value and a maximum value of said electric impulse;

output block electrically communicating with said CPU unit, with said pulse modulator and with said setting unit, said output block transfers the electrical impulse to said commutation block and/or to said at least one pair of electrodes.

Furthermore, in accordance with another preferred embodiment of the present invention, said stimulator further comprises a display, said display is electrically communicating with said CPU unit.

Furthermore, in accordance with another preferred embodiment of the present invention, said setting unit comprises current setting and threshold setting, said current setting is adapted to perform a current adjustment, said threshold setting is adapted to prevent pain during muscular activity by setting a threshold value.

Furthermore, in accordance with another preferred embodiment of the present invention, said setting unit is electrically communicating with a

adhering said reference electrode to the patient in a location relatively remote from the rehabilitated muscles;

connecting said reference electrode to said amplifier;

transmit said electric impulse to the muscles through said at least one pair of electrodes.

Furthermore, in accordance with another preferred embodiment of the present invention, the method further comprises:

receiving electromyographic impulses;

feeding said predetermined threshold value;

comparing said electromyographic impulses to said predetermined threshold value;

transmitting an electric impulse having higher amplitude than the amplitude of the received electromyographic impulse having the highest value to the muscles after said electromyographic impulse exceeds said predetermined threshold value.

And additionally, in another embodiment of the present invention, the method further comprises displaying the transmitted electric impulse on said display and displaying said predetermined threshold value.

## BRIEF DESCRIPTION OF THE FIGURES

Figure 1 illustrates an electrostimulation system with electromyographic and visual biofeedback in accordance with a preferred embodiment of the present invention, attached to a patient through skin electrodes.

Figure 2 illustrates a block diagram of an electrostimulation system with electromyographic and visual biofeedback in accordance with a preferred embodiment of the present invention.

Figure 3 illustrates a block diagram of the stimulator unit shown in Figure 2.

present invention provides an electrostimulation system that produces and transmits impulses to the patient's muscles that facilitate restoring the natural movements of the muscles. Alternately, the system receives EMG voluntary impulses from the patient so that a biofeedback is received. The biofeedback system facilitates the patient to comprehend and distinct between his own will to move the muscle and the actual movements of the muscle.

Reference is now made to Figure 1 illustrating an electrostimulation system with electromyographic and visual biofeedback in accordance with a preferred embodiment of the present invention, attached to a patient through skin electrodes. A dual channel Electrostimulation system with biofeedback 10 may function in three possible modes:

1. Stimulation mode: An electrostimulation system generates specially modulated bipolar currents in two channels simultaneously or intermittently. The electrostimulation system then transmits the stimulating impulses to the patient's muscles through skin surface electrodes according to the needs of the specific patient. The patient receives an impulse that is preferably a train (series) of specially modulated current impulses. Impulse parameters such as duration, repetition rate, maximal amplitude and threshold point can be determined by a therapist.
2. Remote control stimulation mode: similarly to the stimulation mode, however one series of stimulation currents is transmitted and the operation may be remotely activated. In this mode, the patient as well as a therapist may operate the stimulation system upon their will.
3. Biofeedback stimulation mode: operation according to a mode of receiving/transmitting of impulses. An electrostimulation system receives EMG impulses from a patient that voluntarily and gradually tries to activate the muscle according to his own efforts. At a certain predetermined threshold value, the electrostimulation system is triggered to transmit impulses to the muscle. The transmitted impulse has higher values than the received ones. This is a re-educational mode.

produces a weakened action. This impulse is to be amplified by EMG amplifier 106. The amplified impulse is then transferred through filter 110 in order to reduce disturbances and other artifacts. Filter 110 filters out residual electrical activity and furthers on the impulse that is delivered to the muscle by the brain. Possible artifacts from the main electricity system are also removed in this stage. The resulting filtered impulse enters an integrator 112 that integrate the impulse to a dc voltage level that is proportional to the muscle contraction. Integrator 112 is adapted to smooth the impulse and recondition it for visual display and observation. The resulted impulse is then amplified in amplifier 114 to values in which suffice resolution is attained and displayed on display 116. Display 116 is preferably a linear graphic bar display.

The therapist and the patient can see on display 116 the actual voluntary efforts of the patient to produce an action in a specific muscle in order to move a certain organ. The patient becomes involved in the rehabilitation process since he may observe his evolving efforts to move an organ. Display 116 displays also a threshold value that indicates a certain predetermined value to which the patient should be motivated to reach. Since the patient may see on display 116 the result of his real efforts to move an organ and the value to which he should reach, he is totally participating in the rehabilitation process and may be fully motivated and committed to its success. The threshold value may be varied according to the will, the advancement, the ability and the state of a specific patient by the therapist. The threshold value is fed to display 116 from trigger setting 118, which transfers this value also to a comporator 120.

Comporator 120 receives information from two sources: the threshold value from trigger setting 118 and values from amplifier 114 indicating the actual activity of the muscle. Comporator 120 is adapted to instruct commutation block 102 to change the mode of action from muscle impulse receiving to stimulating impulse transmitting when the values transferred from amplifier 114 reach the threshold value in trigger setting 118. The patient, after making a successful effort to reach a predetermined impulse value, is stimulated by a certain current that establishes a reaction or movement of an

twisted into directions that are not usually performed by healthy subjects. Patients experimentally treated by the stimulator of the present invention report that the stimulation is relatively delicate and it lessens significantly the natural fear patients feel in such treatments. This also enhances the motivation of patients towards the stimulation treatments.

The most widely used impulses that are used in neuro-muscular stimulation are electric current impulses. The most effective form of electric impulse is a rectangular form. Reference is now made to Figure 4 illustrating a usual rectangular impulse that may be used in the electrostimulation system with electromyographic and visual biofeedback of the present invention. Bipolar impulses are used in order to prevent polarization of the electrodes; thus the quantity of electricity (defined as the current multiplied by duration of the impulse) that is used in the negative and the positive parts of the impulse should be almost equal. As a result of an impulse shown in Figure 4, the spreading excitation in the muscle may start before the end of the first impulse (the positive part), depending on the duration of the impulse. As a result, when the second part of the impulse having the inverse polarity is being transferred, there will be no response to it.

Reference is now made to Figure 5, illustrating a usual rectangular impulse with a delay. The muscles are excited from the impulse through nerve fibers. Only a part of the fibers won't be excited from the impulse since they have a higher threshold. During the first positive part of the impulse, changes in the membrane potential of this nerve's fibers will not reach the threshold and as a consequence, will not cause a spreading excitation. However, some of these nerve fibers, for which the influence of the impulse is relatively close to their threshold, generate local active potential. While those local potentials are developing, they can reach the threshold and cause a spreading action potential even though the first part of the impulse had already ended. It is desirable that the second impulse part, which has an inverse polarity, will not inhibit the local active potential from reaching the threshold and cause the increase in the quantity of excited fibers. For that reason, the second part

Usually, there is a large dispersion of individual threshold values. It is possible that the physiotherapist will set the starting level of the impulse amplitude above the threshold level or even above the level that causes the maximal response of the muscle. As a result, the patient may feel discomfort or even pain and his motivation to receive the electrostimulation treatment decreases. The decrease in the motivation of the patient influences directly the effectiveness of the treatment. This problem usually arises when the amplitude of the stimulating impulses is regulated using a single scale with absolute units (mA or V). In order to avoid this problem, the method and device of the present invention suggests setting and adjusting the amplitude of the stimulating impulses using two regulators: a threshold regulator and multiplier regulator. The threshold regulator changes the amplitude of stimulation impulses in the range of low amplitudes (for example from 0 to 25 mA) in order to set the amplitude of impulses equal to individual threshold value for sensitivity. The multiplier regulator for setting a strength of muscle contraction is set by the multiplier in the range from 1 to 3 relative threshold units. Using a large range of impulses with amplitude of 4.5 threshold units will probably cause painful irritation.

Reference is now made to Figures 8 and 9 illustrating duration of muscle contraction in accordance with preferred embodiments of the present invention. Both figures depict the bounding curve of the amplitude of bipolar impulses and the muscle contraction dynamics. Curve that is marked with the number 1 is the bounding curve of the amplitude of bipolar impulses and the curve marked with the number 2 is the bounding curve of the amplitude of muscle contraction. Iio is the threshold impulses amplitude and Am, Tm are the amplitude and duration of muscle contraction, respectively.

Returning to Figure 3, pulse modulator 200 transfers the information regarding the type of pulse and its shape to an amplitude modulator 202 that acts as a D/A converter. The generated impulse built in accordance to the preferred sequence shown herein before from both modulators, pulse modulator 200 and amplitude modulator 202, interacts with a setting cycle that accords the impulse to a specific patient. The parameters, $A_{io}$max, Ts and

the resulting output pulses to surface electrodes 100 of CH1 via commutation block 102 (shown in Figure 2) directly through CH2.

CPU unit 212 receives predetermined parameters of stimulation from a controller block 214. The processor is also electrically communicating with a display 216 on which the type and shape of the constructed pulse may be displayed as well as other information regarding the treatment.

The electrostimulation system with electromyographic and visual biofeedback carries precaution measures by currying out a self-test before the treatment begins and provides automatic emergency shutdown, in case of fault conditions.

The electrostimulation system with electromyographic and visual biofeedback is preferably powered by internal Nickel Metal rechargeable battery.

It should be clear that the description of the embodiments and attached Figures set forth in this specification serves only for a better understanding of the invention, without limiting its scope as covered by the following Claims.

It should also be clear that a person skilled in the art, after reading the present specification could make adjustments or amendments to the attached Figures and above described embodiments that would still be covered by the following Claims.

3. The electrostimulation system a claimed in Claim 1, wherein an integrator is electrically communicating with said filtering unit, said integrator is adapted to smooth and recondition the electromyographic impulse that is received from said filtering unit so that the impulse may be displayed on said display.

4. The electrostimulation system as claimed in Claim 3, wherein an additional amplifier is electrically communicating with said integrator and with said display so that the electromyographic impulse outgoing from said integrator to said display is further amplified.

5. The electrostimulation system as claimed in Claim 1, wherein said predetermined threshold value is manually fed to said display by a trigger setting.

6. The electrostimulation system as claimed in Claim 5, wherein a comporator is electrically communicating with said trigger setting as well as with said amplifier.

7. The electrostimulation system as claimed in Claim 6, wherein said comporator is adapted to change a mode of said commutation block from transferring the electromyographic impulses to said amplifier to transferring the generated electric impulse from said stimulator when the electromyographic impulse reaches said predetermined threshold value.

8. The electrostimulation system as claimed in Claim 1, wherein a remote control unit is communicating with said control unit.

9. The electrostimulation system as claimed in Claim 1, wherein said display is a linear graphic bar display.

14. A method for stimulating muscles that are in a rehabilitation process of a patient, said method comprising:

providing an electrostimulation system with electromyographic and visual biofeedback that comprises

a stimulator adapted to generate an electric impulse;

at least one pair of electrodes adapted to transmit said electric impulse or to receive electromyographic impulses;

amplifier electrically communicating with said at least one pair of electrodes, said amplifier adapted to amplify said received electromyographic impulses;

filtering unit electrically communicating with said amplifier, said filtering unit is adapted to remove artifacts from the received electromyographic impulse.

commutation block electrically communicating with said at least one pair of electrodes, said commutation block adapted to alternately transfer the electromyographic impulses to said amplifier or to transfer the generated electric impulse from said stimulator;

display for displaying said received electromyographic impulses and a predetermined threshold value;

a control unit adapted to receive the electromyographic impulses from said amplifier and to activate said stimulator in a predetermined manner;

adhering said a least one pair of electrodes to the rehabilitated muscles;

providing a reference electrode;

adhering said reference electrode to the patient in a location relatively remote from the rehabilitated muscles;

connecting said reference electrode to said amplifier;

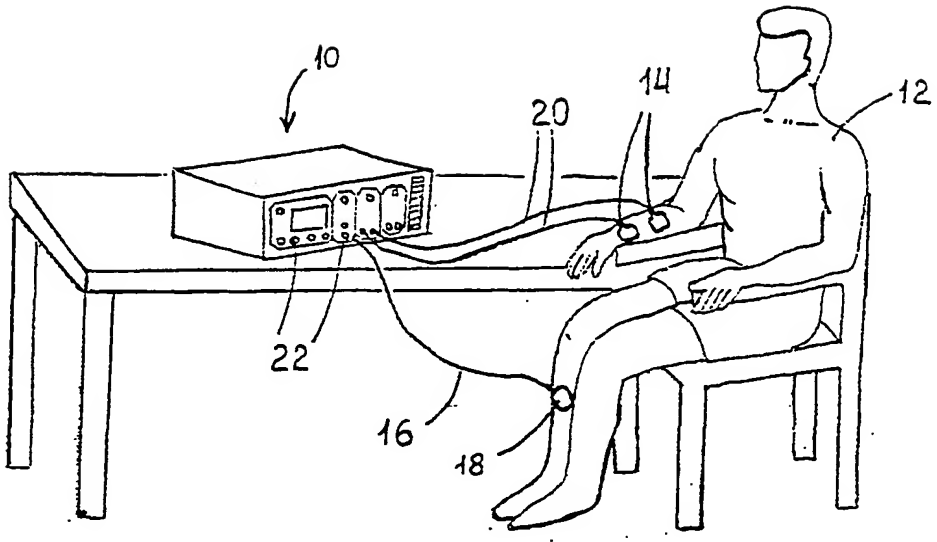


Figure 1

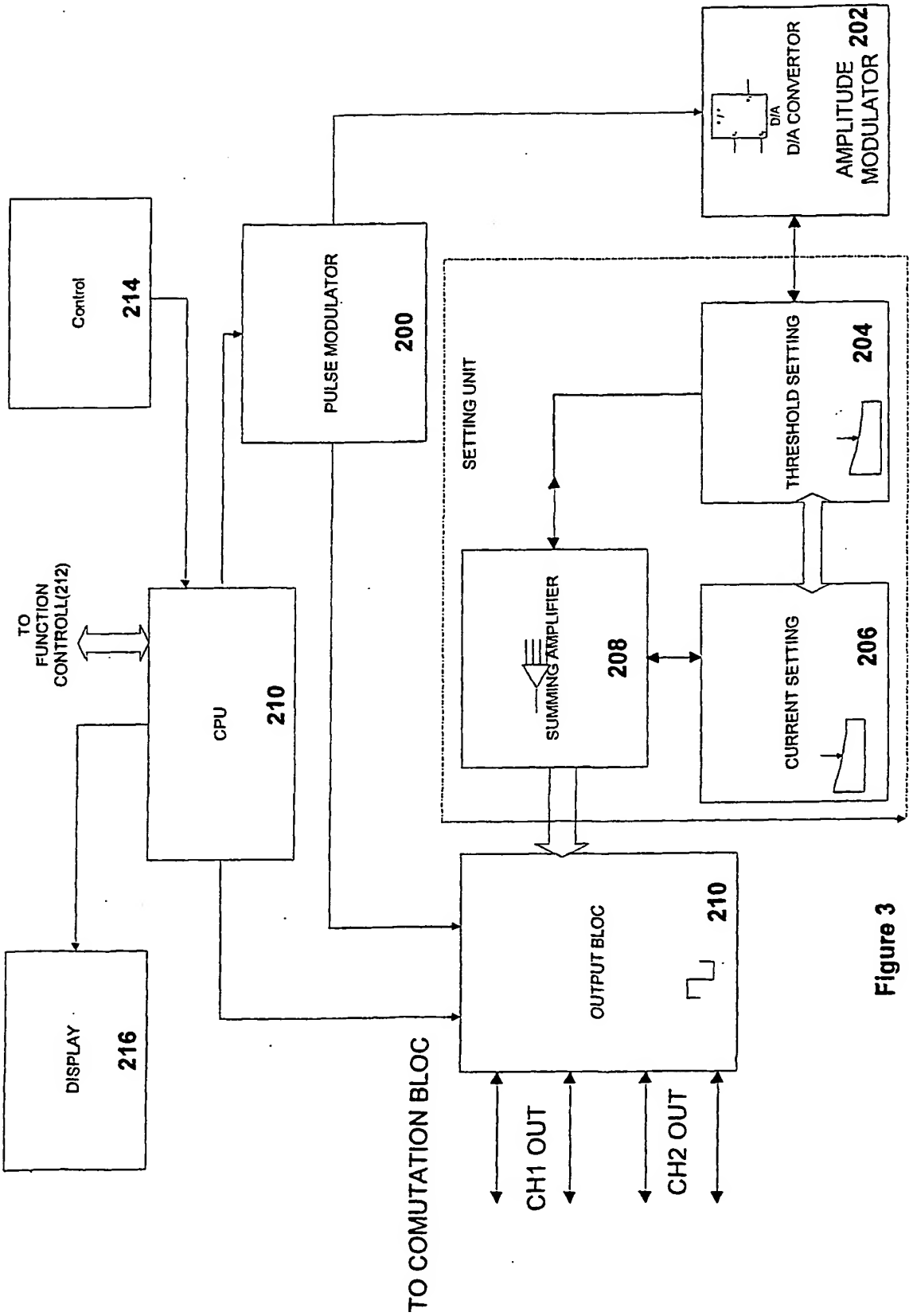
AMPLITUDE MODULATOR 202
D/A
D/A CONVERTOR
Control 214
PULSE MODULATOR 200
SETTING UNIT
THRESHOLD SETTING 204
TO FUNCTION CONTROLL(212)
CPU 210
SUMMING AMPLIFIER 208
CURRENT SETTING 206
DISPLAY 216
OUTPUT BLOC 210
TO COMUTATION BLOC
CH1 OUT
CH2 OUT

Figure 3

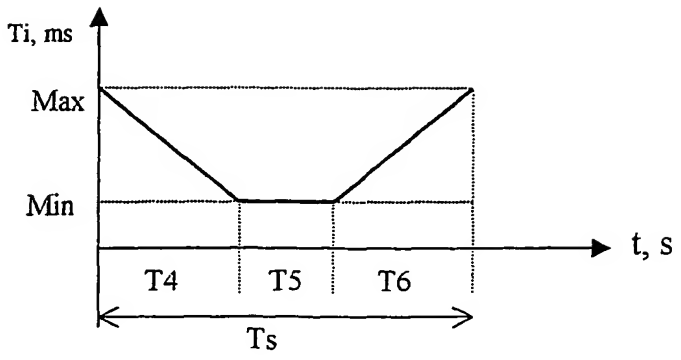
Ti, ms
Max
Min
t, s
T4
T5
T6
Ts

Fig.7.

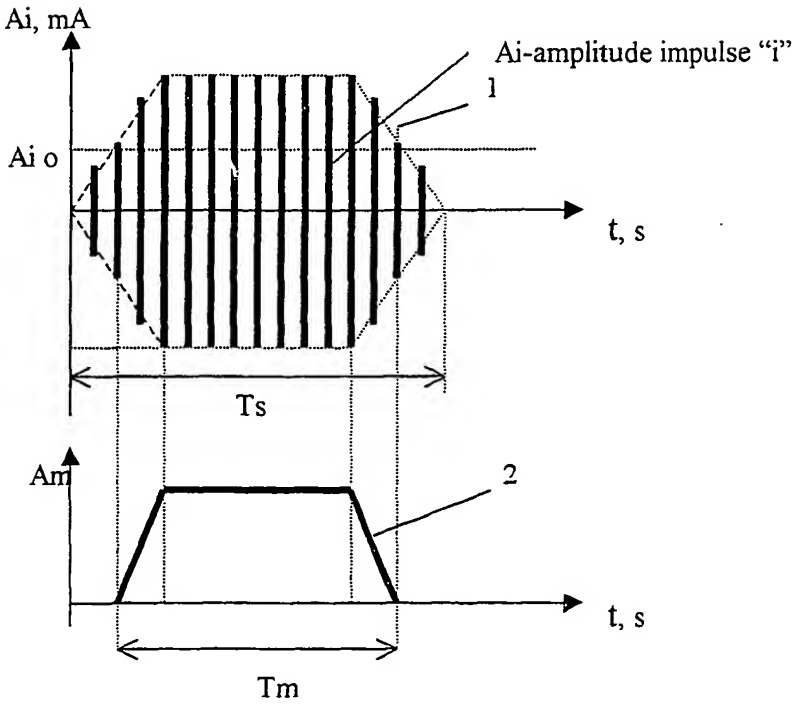
Ai, mA
Ai-amplitude impulse "i"
1
Ai o
t, s
Ts
Am
2
t, s
Tm

Fig 8.

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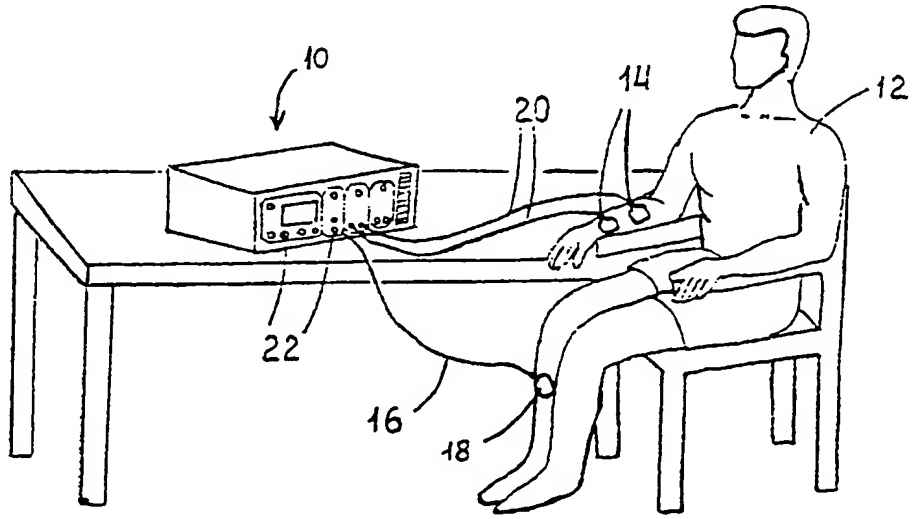


(57) Abstract: An electrostimulation system with electromyographic and visual biofeedback (10) for sensing electromyographic impulses and facilitating muscular activity. The system comprises a stimulator for generating and electric impulse and at least one pair of electrodes (14) adapted to transmit an electric impulse or receive electromyographic impulses. The stimulator transmits impulses when an electromyographic impulse substantially equals or exceeds the predetermined threshold value.

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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL01/00752

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos..
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 17-18
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

The scope of the claims is indeterminate.

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.